

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Zeger DEBYSER et al.	Confirmation No.:	6752
Serial No.:	10/529,508	Art Unit:	1635
Filing Date:	June 27, 2005	Examiner:	L. V. Wollenberger
		Customer No.:	21559
Title:	INTEGRASE COFACTOR		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION TO CORRECT FILING RECEIPT

Applicant requests that the enclosed filing receipt be corrected as follows.

In the “**Applicant(s)**” section, please change the residence of inventor Petr Cherepanov to read “Brugge, BELGIUM.”

In the “**Foreign Applications**” section, please change the filing date of British Patent Application 0222361.8 to read “09/26/2002.”

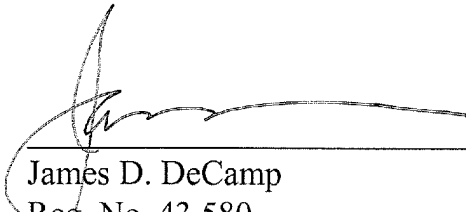
Enclosed are copies of the incorrect filing receipt, the Application Data Sheet and Preliminary Amendment as filed on March 28, 2005, and the Combined Declaration and Power of Attorney as submitted on June 24, 2005, which includes the address of inventor Petr Cherepanov.

If there are any charges or any credits, please apply them to Deposit Account No.

03-2095.

Respectfully submitted,

Date: 15 February 2007

  
\_\_\_\_\_  
James D. DeCamp  
Reg. No. 43,580

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/529,508	06/27/2005	1646	990	50304/072001	12	27	6

CONFIRMATION NO. 6752

21559  
 CLARK & ELBING LLP  
 101 FEDERAL STREET  
 BOSTON, MA 02110

DE-DOCKETED

## FILING RECEIPT



\*OC000000020201340\*

Date Mailed: 08/29/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

## Applicant(s)

Zeger Debyser, Heverlee, BELGIUM;  
 Petr Cherepanov, Brookline, MA; *Brugge, BELGIUM*  
 Erik De Clercq, Lovenjoel, BELGIUM;

## Assignment For Published Patent Application

KULEUVEN RESEARCH AND DEVELOPMENT, Leuven, BELGIUM

**Power of Attorney:** The patent practitioners associated with Customer Number 21559.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/BE03/00164 09/26/2003

## Foreign Applications

UNITED KINGDOM 0222361.8 ~~09/26/2003~~ *09/26/2002*  
 UNITED KINGDOM 0224539.7 10/22/2002

If Required, Foreign Filing License Granted: 08/25/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/529,508**

Projected Publication Date: 12/07/2006

Non-Publication Request: No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

Integrase cofactor

**Preliminary Class**

536

## **PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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### **LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15**

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date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

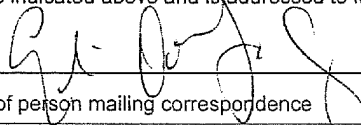
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#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**PATENT**  
**ATTORNEY DOCKET NO. 50304/072001**

Certificate of Mailing	
Date of Deposit: <u>March 28, 2005</u>	Label Number: <u>EV617223462US</u>
<small>I hereby certify under 37 C.F.R. § 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</small>	
<u>Elvis De La Cruz</u>	
Printed name of person mailing correspondence	Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	DEBYSER et al.	Art Unit:	To Be Assigned
Serial No.:	To Be Assigned	Examiner:	To Be Assigned
Filed:	March 28, 2005	Customer No.:	21559
Title:	INTEGRASE COFACTOR		

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination, kindly amend the application as follows.

Amendments to the specification:

On page 1 (line 2) of PCT/BE2003/000164 (WO 2004/029246), insert the following paragraph.

CROSS REFERENCE TO RELATED APPLICATIONS

This application is the U.S. National Stage of International Application No. PCT/BE2003/000164, filed September 26, 2003, which, in turn, claims the benefit of GB 0222361.8 and GB 0224539.7 filed September 26, 2002 and October 22, 2002, respectively.

Amendments to the Claims:

Claims 1-29. (cancelled)

30. (new) A pharmaceutical composition comprising a molecule which comprises a region specifically interacting with protein LEDGF/P75 or a fragment thereof or a nucleic acid encoding said protein or fragment, for the treatment or prevention of viral infections in a mammal.

31. (new) The pharmaceutical composition as in claim 30, wherein said viral infection is an infection with HIV.

32. (new) The pharmaceutical composition as in claim 30, further comprising one or more compounds effective in the treatment or prevention of viral infections.

33. (new) The pharmaceutical composition as in claim 30, wherein said molecule is selected from the group comprising an antibody or any fragment thereof, a peptide, a small molecule, an antisense nucleic acid, an antigene compound, a ribozyme, nucleic acids mediating RNA interference and a variant polypeptide.



34. (new) The pharmaceutical composition as in claim 30, wherein said molecule is a polynucleotide encoding the LEDGF/P75 protein or an intermediate or a fragment of said protein, an allelic variant, a homologue, a portion or a mutation thereof.

35. (new) The pharmaceutical composition as in claim 30, wherein said molecule is a nucleic acid mediating RNA interference specific for mRNA of LEDGF/P75.

36. (new) The pharmaceutical composition as in claim 30, wherein said molecule is a construct mediating gene therapy specific for modifying the expression of LEDGF/P75.

37. (new) The pharmaceutical composition as in claim 30, wherein said molecule is a homologue, a variant, a mutated form or a fragment of the LEDGF/P75 protein.

38. (new) A method of treating or preventing viral infections in a mammal, which method comprises administering to said mammal a molecule which comprises a region specifically interacting with LEDGF/P75 or a fragment thereof or a nucleic acid encoding said LEDGF/P75 or fragment thereof.

39. (new) The method as in claim 38, wherein said molecule is selected from the group comprising an antibody or any fragment thereof, a peptide, a small molecule, an

antisense nucleic acid, an antigene compound, a ribozyme, nucleic acids mediating RNA interference and a variant polypeptide.

40. (new) The method as in claim 38, wherein said molecule is a polynucleotide encoding the LEDGF/P75 protein or an intermediate or a fragment of said protein, an allelic variant, a homologue, a portion or a mutation thereof.

41. (new) The method as in claim 38, wherein said molecule is a nucleic acid mediating RNA interference specific for mRNA of LEDGF/P75.

42. (new) A method as in claim 38, wherein said molecule is a homologue, a variant, a mutated form or a fragment of the LEDGF/P75 protein.

43. (new) A method as in claim 38, wherein said viral infection is an infection with HIV.

44. (new) A method of drug discovery comprising the step of exposing said molecule to the protein LEDGF/P75 or a nucleic acid encoding said LEDGF/P75.

45. (new) The method of claim 44, which comprises screening of molecules for their antiviral activity, by exposing said molecules to the protein LEDGF/P75 or a nucleic acid encoding said LEDGF/P75.

46. (new) The method of claim 44, further comprising the step of determining the binding or hybridisation of said molecule(s) to said protein LEDGF/P75 or said nucleic acid.

47. (new) The method of claim 44, further comprising the step of determining the binding of said molecules to binding places of said protein LEDGF/P75 on lentiviral integrase or to the complex of said protein LEDGF/P75 with lentiviral integrase.

48. (new) The method of claim 44, which comprises the step of monitoring the prevention or suppression of retroviral replication or integration.

49. (new) The method of claim 44, comprising the modulation of the nuclear transport of lentiviral integrase.

50. (new) The method of claim 44, comprising the step of increasing the solubility of the lentiviral integrase and/or the step of crystallisation of the lentiviral integrase.

51. (new) A method for modulating the interaction of LEDGF/P75 with lentiviral integrase, which comprises the use of a molecule comprising a region specifically interacting with said protein LEDGF/P75 or nucleic acids encoding said protein or with fragments, allelic variants, a homologue, a portion or mutations of the protein or nucleic acids.

52. (new) A polynucleotide comprising a first polynucleotide encoding the LEDGF/P75 protein or an intermediate or a fragment of said protein, a variant, a mutation thereof, further comprising a second polynucleotide which encodes at least a portion of an HIV integrase.

53. (new) The polynucleotide of claim 52, wherein said first and said second polynucleotides are arranged in such a way that a fusion protein results after expression.

54. (new) An isolated protein complex comprising a retroviral integrase and the LEDGF/P75 protein or a fragment, a variant, or a mutation thereof.

55. (new) The isolated protein complex of claim 54 wherein said retroviral integrase is a lentiviral integrase.

56. (new) The isolated complex of claim 54, wherein the retroviral integrase is the HIV integrase.

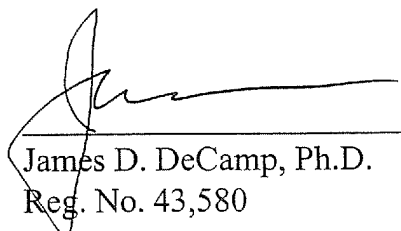
## REMARKS

Applicants have amended the claims as filed in the international application to remove multiple dependencies. Applicants note that there is no intention to abandon any subject matter with regard to the deleted matter. Applicants also amend the specification to cross-reference related applications. A courtesy copy of the present specification is enclosed, but the World Intellectual Property Office (WIPO) copy should be relied upon if it is already present in the U.S. Patent Office file. No new matter has been added by the present amendment.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 28 March 2005



James D. DeCamp, Ph.D.  
Reg. No. 43,580

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045

## Application Data Sheet

### Application Information

Application number::

Filing Date:: 03/28/05

Application Type:: Regular

Subject Matter:: Utility

Suggested Classification::

Suggested Group Art Unit::

CD-ROM or CD-R?:: No

Number of CD disks::

Number of copies of CDs::

Sequence submission?:: No

Computer Readable Form (CRF)?:: No

Number of copies of CRF::

Title:: INTEGRASE COFACTOR

Attorney Docket Number:: 50304/072001

Request of Early Publication?:: No

Request of Non-Publication?:: No

Suggested Drawing Figure:: 12

Total Drawing Sheets:: 12

Small Entity?:: Yes

Petition Included?:: No

Petition Type::

Licensed US Govt. Agency::

Contract or Grant Numbers::

Secrecy Order in Parent Appl.?:: No

**Applicant Information**

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Belgium

Status:: Full Capacity

Given Name:: Zeger

Family Name:: DEBYSER

City of Residence:: Heverlee

State or Province of Residence::

Country of Residence:: Belgium

Street of mailing address:: Korbeek-Losestraat 108

City of mailing address:: Heverlee

State or Province of mailing address::

Country of mailing address:: Belgium

Postal or Zip Code of mailing address:: B-3001

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Russia

Status:: Full Capacity

Given Name:: Petr

Family Name:: CHEREPANOV

City of Residence:: Brookline

State or Province of Residence:: MA

Country of Residence:: United States



Street of mailing address:: 32 Saint Paul Street, Apt. 1  
City of mailing address:: Brookline  
State or Province of mailing address:: MA  
Country of mailing address:: United States  
Postal or Zip Code of mailing address:: 02446

Applicant Authority Type:: Inventor  
Primary Citizenship Country:: Belgium  
Status:: Full Capacity  
Given Name:: Erik  
Family Name:: DE CLERCQ  
City of Residence:: Lovenjoel  
State or Province of Residence::  
Country of Residence:: Belgium  
Street of mailing address:: Parklaan 9  
City of mailing address:: Lovenjoel  
State or Province of mailing address::  
Country of mailing address:: Belgium  
Postal or Zip Code of mailing address:: B-3360

**Correspondence Information**

Correspondence Customer Number:: 21559

**Representative Information**

Representative Customer Number:: 21559

**Domestic Priority Information**

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National stage of	PCT/BE2003/000164	09/26/2003

### **Foreign Priority Information**

Country::	Application Number::	Filing Date::	Priority Claimed::
GB	0222361.8	09/26/2002	YES
GB	0224539.7	10/22/2002	YES

### **Assignee Information**

Assignee name::

Street of mailing address::

City of mailing address::

State of Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **INTEGRASE COFACTOR**, the specification of which is that of PCT International Application No. PCT/BE2003/000164, filed on September 26, 2003.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I acknowledge the duty to disclose all information I know to be material to patentability in accordance with 37 C.F.R. § 1.56.

**FOREIGN PRIORITY RIGHTS:** I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or (f), or § 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below, and have also identified below any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Country	Serial Number	Filing Date	Priority Claimed?
GB	0222361.8	September 26, 2002	Yes
GB	0224539.7	October 22, 2002	Yes

**PROVISIONAL PRIORITY RIGHTS:** I hereby claim priority benefits under 35 U.S.C. § 119(e) of any United States provisional patent application(s) listed below filed by an inventor or inventors on the same subject matter as the present application and having a filing date before that of the application(s) of which priority is claimed:

Serial Number	Filing Date	Status

**NON-PROVISIONAL PRIORITY RIGHTS:** I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information I know to be material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

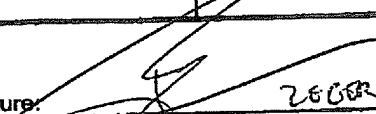
Serial Number	Filing Date	Status

I hereby appoint the attorneys and/or agents associated with customer number **21559** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence relating to this application to the address associated with customer number **21559**.

Address all telephone calls to: James D. DeCamp, Ph.D. at 617-428-0200.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Zeger DEBYSER	Heverlee, Belgium BEX	Korbeek-Losestraat 108 B-3001 Heverlee Belgium	Belgium
Signature:  Zeger DEBYSER			Date: 27/4/05

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Petr CHEREPANOV	Brookline, MA United States	32 Saint Paul Street, Apt. 1 Brookline, MA 02446 United States	Russia
Signature:			Date:

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Erik DE CLERCQ	Lovenjoel, Belgium	Parklaan 9 B-3360 Lovenjoel Belgium	Belgium
Signature:			Date:

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **INTEGRASE COFACTOR**, the specification of which is that of PCT International Application No. PCT/BE2003/000164, filed on September 26, 2003.

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Serial Number	Filing Date	Status

2-00 Petr Cherepanov; Postal address: Oud-Strijderslaan 9, 8200 St-Andries, Bex  
Brugge, Belgium  
Citizen of Russian Federation; *Zy*

I hereby appoint the attorneys and/or agents associated with customer number 21559 to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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Address all telephone calls to: James D. DeCamp, Ph.D. at 617-428-0200.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Zeger DEBYSER	Heverlee, Belgium	Korbeek-Losestraat 108 B-3001 Heverlee Belgium	Belgium
Signature:			Date:

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Petr CHEREPANOV	Brookline, MA United States	32 Saint Paul Street, Apt. 1 Brookline, MA 02446 United States	Russia
Signature:			Date:

Full Name (First, Middle, Last)	Residence Address (City, State, Country)	Post Office Address (Street, City, State, Country)	Country of Citizenship
Erik DE CLERCQ	Lovenjoel, Belgium	Parklaan 9 B-3360 Lovenjoel Belgium	Belgium
Signature:			Date:

**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **INTEGRASE COFACTOR**, the specification of which is that of PCT International Application No. PCT/BE2003/000164, filed on September 26, 2003.

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Serial Number	Filing Date	Status

I hereby appoint the attorneys and/or agents associated with customer number 21559 to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

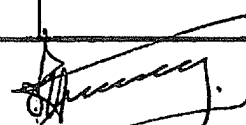
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Address all telephone calls to: James D. DeCamp, Ph.D. at 617-428-0200.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

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